

RFE MEMO

Page 1 of 1

Product Description(s): V-PLEX® and V-PLEX Plus Human VEGF Kit

Catalog Number(s) / Size(s): K151RH-Series, K156RH-Series

Lot Number: K0080879

Based on additional testing, the original date of expiration for this kit has been extended by 12 months. The expiration date of K0080879 has been extended to 31 JUL 2020.

The expiration date for the following kit component has been extended:

| Description | Lot Number | Original Expiration Date | New Expiration Date |
|-----------------------|------------|--------------------------|---------------------|
| Human VEGF Plate | Z0056036 | 31 JAN 2020 | 31 JUL 2020 |
| Anti-hu VEGF Antibody | D0080894 | 31 JUL 2019 | 31 JUL 2020 |
| Diluent 43 | M0430023 | 31 DEC 2019 | 31 JUL 2020 |
| Diluent 3 | M0030078 | 31 JAN 2020 | 31 JUL 2020 |

| Function | Name | Signature | Date |
|----------|---------------|---------------|-------------|
| Quality | Karen Hamilla | Karen Hamille | 21 JAN 2020 |

This memo supersedes all other statements regarding date of expiration for this product.

Memo Rev. B CM-00289-B

CERTIFICATE OF ANALYSIS

Page 1 of 2

Product Description: V-PLEX® and V-PLEX Plus NHP VEGF Kit

Kit Catalog Numbers: K156RH-Series

Kit Lot Number: K0080879
Expiration Date: 31 Jul 2019

Acceptance Data/ Percent Recovery Specifications:

| | | Calibrator | | Cytokine Panel 1 (human) Control 1 | | Cytokine Panel 1 (human) Control 2 | | Cytokine Panel 1 (human) Control 3 | |
|------|----------|------------|-------|---------------------------------------|-------|---------------------------------------|-------|---------------------------------------|-------|
| Spot | Name | Recovery | CV | Recovery | CV | Recovery | CV | Recovery | CV |
| 1 | NHP VEGF | 80% - 120% | < 20% | 80% - 120% | < 20% | 80% - 120% | < 20% | 80% - 120% | < 20% |

| | | LLOQ | | | ULOQ | | |
|------|----------|-------|------------|-------|-------|------------|-------|
| Spot | Name | Value | Recovery | CV | Value | Recovery | CV |
| 1 | NHP VEGF | 7.70 | 80% - 120% | < 20% | 562 | 80% - 120% | < 20% |

Stock Concentration of Material Tested:

| Spot | Name | Item | Conc | Units |
|------------|------------------------------------|------------------------------------|-------|-------|
| 1 NHP VEGF | Calibrator | 1340 | pg/mL | |
| | Cytokine Panel 1 (human) Control 1 | 373 | pg/mL | |
| | Cytokine Panel 1 (human) Control 2 | 127 | pg/mL | |
| | | Cytokine Panel 1 (human) Control 3 | 56.1 | pg/mL |

Controls tested may not be the same lot as shipped.

The calibrator and controls for this assay contain a human recombinant cytokine calibrator sequence that is highly homologous to the non-human primate cytokine. This assay has been verified to cross-react with homologs of rhesus and cynomolgus monkeys. See Product Insert for experimental data.

Standard Curve Data:

| NHP VEGF - Spot 1 | | | | |
|-------------------|---------------|-----|--|--|
| Conc. pg/mL | ECL Signal | %CV | | |
| 1340 | 286,000 | 1.3 | | |
| 335 | 56,300 | 1.8 | | |
| 83.8 | 11,800 | 1.9 | | |
| 20.9 | 2,720 | 1.0 | | |
| 5.23 | 729 | 2.7 | | |
| 1.31 | 220 | 3.1 | | |
| 0.327 | 95 | 3.4 | | |
| 0.00 | 53 | 8.1 | | |

CERTIFICATE OF ANALYSIS

Page 2 of 2

Components:

| Description | Lot Number | Storage Temperature | Expiration Date |
|---|------------------|---------------------|-----------------|
| Human VEGF Plate | Z0056036 | 2-8°C | 31 Jan 2020 |
| Anti-hu VEGF Antibody | D0080894 | 2-8°C | 31 Jul 2019 |
| Cytokine Panel 1 (human) Calibrator Blend | A0080108 | 2-8°C | 30 Nov 2021 |
| Diluent 43 | M0430023 | ≤ -10°C | 31 Dec 2019 |
| Diluent 3 | M0030078 | ≤ -10°C | 31 Jan 2020 |
| MSD Read Buffer T | Not Kit Specific | Not Kit Specific | N/A |

| Additional Components Included in V-PLEX Plus | | | | |
|---|------------------|--|--|--|
| Plate Seals | Not Kit Specific | | | |
| Wash Buffer (20X), 100 mL | Not Kit Specific | | | |
| Cytokine Panel 1 (human) Control 1 | Not Kit Specific | | | |
| Cytokine Panel 1 (human) Control 2 | Not Kit Specific | | | |
| Cytokine Panel 1 (human) Control 3 | Not Kit Specific | | | |

Statement:

The above product is intended for Research Use Only. Not for use in Diagnostic Procedures.

| | Name | Function | Signature | Date |
|-----------------|--------------|-------------------|--------------|-------------|
| Review/Approval | Dawn Stollar | Quality Assurance | Dawn Stollar | 01 DEC 2017 |